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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/846,933	04/30/1997	JEFFREY L. CLELAND	P0825BC3	9920

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	35

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/846,933	CLELAND ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-9 and 23-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-9 and 23-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment received March 4, 2002 has been entered. Claims 1, 4-9 and 23-28 are under consideration in this office action.

Withdrawal of Rejections

2. The rejection of claims 1, 4-9 and 23-28 under 35 U.S.C. 103(a) has been withdrawn in view of applicants amendments and arguments.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 4-9 and 23-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 1 is drawn to a composition comprising a homogeneous population of polylactide or poly(lactide-co-glycolide) PLGA polymer microspheres encapsulating an

antigen wherein the homogeneous population is produced from an emulsion and the microsphere in the homogeneous population have a triphasic in vitro antigen release profile.

The written description in this case only sets forth specific encapsulated mixtures of about two to 50 PLGA microsphere populations (page 6 lines 18-20). The specification further states that the antigen is released in a triphasic pattern. The specification does not state that the microspheres are a homogeneous population wherein each population has a triphasic release profile. The specification antigen is release in an initial burst and the remaining antigen is released in a second burst in one microsphere population, after about 1 to 30 days; thus there appears to be a total of two release occasions. In a second microsphere population after about 30 to 90 days; thus there is one slow phase release occasion, and in additional microspheres populations after about 90 to 180 days; thus there is one release occasion (page 6 lines 28-3). There is no teaching of a single homogeneous population with three release times, rather the specification teaches individual microsphere populations that are combined to create triphasic release profiles.

Therefore the written description is not commensurate in scope with the claims drawn to a composition comprising a homogeneous population of polylactide or poly(lactide-co-glycolide) PLGA polymer microspheres encapsulating an antigen wherein the homogeneous population is produced from an emulsion and the microsphere in the homogeneous population have a triphasic in vitro antigen release profile. Neither the specification nor the claims teach a composition comprising a homogeneous population of polylactide or poly(lactide-co-glycolide) PLGA polymer microspheres encapsulating an antigen wherein the homogeneous population is produced from an emulsion and the microsphere in the homogeneous population has a

triphasic in vitro antigen release profile. There is no homogeneous population of microspheres rather there are individual microsphere population with different release profiles. Neither the claims nor the specification teach how to obtain a composition comprising a homogeneous population of polylactide or poly(lactide-co-glycolide) PLGA polymer microspheres encapsulating an antigen wherein the homogeneous population is produced from an emulsion and the microsphere in the homogeneous population have a triphasic in vitro antigen release profile. The specification does not include structural examples of a composition comprising a homogeneous population of polylactide or poly(lactide-co-glycolide) PLGA polymer microspheres encapsulating an antigen wherein the homogeneous population is produced from an emulsion and the microsphere in the homogeneous population has a triphasic in vitro antigen release profile, rather the specification teaches individual microsphere populations with at best two release times as its release profile. Thus, the resulting compositions could result in complexes not taught and enabled by the specification.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

It is noted that applicants' arguments point out that each population is homogeneous with respect to the release profile, thereby inherently stating that there are individual populations comprised within the claimed "homogeneous population" and

that there is not a single homogeneous population of microspheres as asserted by applicants'. Applicants assert that one skilled in the art understands that the description relates to a composition in which multiple homogeneous microsphere populations can be combined to give a composition that has a release profile with more than three phases. The examiner agrees that multiple homogeneous microsphere populations can be combined to create a composition that has a release profile with three release phases, however what is not taught is one homogeneous population with a triphasic release profile.

The skilled artisan cannot envision the detailed structure of the claimed composition, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. Furthermore, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus. Therefore the full breadth of the claim fails to meet the written description provision of 35 USC 112, first paragraph.

New Matter Rejection

4. Claims 1, 4-9 and 23-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Neither the specification nor originally presented claims provides support for a composition comprising a homogeneous population of polylactide or poly(lactide-co-glycolide) PLGA polymer microspheres encapsulating an antigen wherein the homogeneous population is produced from an emulsion and the microsphere in the homogeneous population has a triphasic in vitro antigen release profile.

Applicant did not point to support in the specification for a composition comprising a homogeneous population of polylactide or poly(lactide-co-glycolide) PLGA polymer microspheres encapsulating an antigen wherein the homogeneous population is produced from an emulsion and the microsphere in the homogeneous population has a triphasic in vitro antigen release profile. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of a composition comprising a homogeneous population of polylactide or poly(lactide-co-glycolide) PLGA polymer microspheres encapsulating an antigen wherein the homogeneous population is produced from an emulsion and the microsphere in the homogeneous population has a triphasic in vitro antigen release profile.

Thus, there appears to be no teaching of a composition comprising a homogeneous population of polylactide or poly(lactide-co-glycolide) PLGA polymer microspheres encapsulating an antigen wherein the homogeneous population is produced from an emulsion and the microsphere in the homogeneous population has a triphasic in vitro antigen release profile.

Applicants' have pointed to pages 5-7 of the instant specification and prior claims for support of the composition comprising a homogeneous population of polylactide or poly(lactide-co-glycolide) PLGA polymer microspheres encapsulating an antigen wherein the homogeneous population is produced from an emulsion and the microsphere in the homogeneous population has a triphasic in vitro antigen release profile, however it appears that the entire specification fails to recite support for the newly recited composition comprising a homogeneous population having triphasic in vitro antigen release profile. The support that applicants' point to provides that individual populations can be combined to create a triphasic release profile. Contrary to applicants' arguments there is no single homogeneous population of microspheres taught by the instant specification.

Therefore, it appears that there is no support in the specification. Applicants must specifically point to page and line number support for the identity of a composition comprising a homogeneous population of polylactide or poly(lactide-co-glycolide) PLGA polymer microspheres encapsulating an antigen wherein the homogeneous population is produced from an emulsion and the microspheres in the homogeneous population has a triphasic in vitro antigen release profile as recited by the amendments. Therefore, the new claims incorporate new matter and are accordingly rejected.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
March 15, 2004

MARK NAVARRO
PRIMARY EXAMINER